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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,184	06/20/2003	Garner T. Haupert JR.	0838.2003-001	6779

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EXAMINER	
SCHWADRON, RONALD B	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/601,184	HAUPERT ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-8 and 10-23* is/are pending in the application.

4a) Of the above claim(s) *3 and 10-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of 5beta pregnane 3,20 dione in the reply filed on 1/24/08 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons.
The MPEP section 803.02 states:
In applications containing a Markush-type claim that encompasses at least two independent or distinct inventions, the examiner may require a provisional election of a single species prior to examination on the merits.
The compounds recited in claim are chemically and structurally distinct.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries) and/or the prior art applicable to one species would not likely be applicable to another species.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1,2,4,6-8 are under consideration.

3. The previous objection to claims 5/9 as per enunciated in the Office Action of 12/28/06, paragraph 6 is withdrawn in view of the cancellation of claims 5/9.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

> make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 1,2,4,6,7,8 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the Office Action of 12/28/06, paragraph 8 is withdrawn in view of the amended claims.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The rejection of claims 1,2,4-9 under 35 U.S.C. 103(a) as being unpatentable over Parhami-Seren et al. (WO 01/25281) in view of Hughes et al. (WO 01/03687), Lu et al. and Nussdorfer et al. for the reasons elaborated in the Office Action of 12/28/06 is withdrawn in view of the amended claims and cancellation of claims 5/9.

8. Claims 1,2,4,6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parhami-Seren et al. (WO 01/25281) in view of Hughes et al. (WO 01/03687), Lu et al., Kawamura et al. and Gartner et al.
Parhami-Seren et al. teach that antibodies against the steroid OLC (aka HIF, see page 1, first paragraph) can be used to treat hypertension (see page 6, first complete paragraph). The method would have been used to treat any form of hypertension involving OLC such as essential hypertension (see Parhami-Seren et al.). Parhami-Seren et al. teach methods for making and identifying such antibodies (see page 9). Parhami-Seren et al. do not teach the claimed method wherein the antibody identified and used would be against a molecule in the HIF biosynthetic pathway. Hughes et al. discloses that an inhibitor of enzymatic activity involved in the biosynthesis of a steroid molecule can be used to prevent synthesis of said molecule and therefore treat a disease mediated by said molecule (see abstract, page 1, lines 8-10). Lu et al. disclose that EO (aka OLC/HIF) is a steroid molecule that is formed from pregnenolone/progesterone (see abstract). Kawamura et al. disclose that ouabain and HIF are the same molecule (see page 6659, first column, last paragraph). Gartner et al. disclose that all steroid cardenolides (aka ouabain)

are 5beta configured (see page 239, second column). Gartner et al. disclose that such molecules are formed via an initial reaction of progesterone to form 5Beta pregnane-3,20 dione (see page 239, second column). Since Liu et al. disclose that OLC/HIF is a steroid molecule that is formed from pregnenolone/progesterone and Kawamura et al. disclose that ouabain and HIF are the same molecule, wherein ouabain is a 5beta configured cardenolide, it would have been apparent that 5Beta pregnane-3,20 dione was an intermediary in the formation of ouabain/HIF because Gartner et al. disclose that such molecules are formed via an initial reaction of progesterone to form 5Beta pregnane-3,20 dione. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Parhami-Seren et al. teach that antibodies against the steroid OLC (aka HIF) can be used to treat hypertension and methods for making and identifying such antibodies whilst Hughes et al. discloses that an inhibitor of enzymatic activity involved in the biosynthesis of a steroid molecule can be used to prevent synthesis of said molecule and therefore treat a disease mediated by said molecule, while the Liu et al. disclose that OLC/HIF) is a steroid molecule that is formed from pregnenolone/progesterone and Kawamura et al. disclose that ouabain and HIF are the same molecule, wherein ouabain is a 5beta configured cardenolide, and therefore it would been apparent that 5Beta pregnane-3,20 dione was an intermediary in the formation of ouabain/HIF (in view of the teaching of Gartner et al. that all steroid cardenolides (aka ouabain) are 5beta configured and that such molecules are

formed via an initial reaction of progesterone to form 5Beta pregnane-3,20 dione). One of ordinary skill in the art would have been motivated to do the aforementioned because Hughes et al. discloses that an inhibitor of enzymatic activity involved in the biosynthesis of a steroid molecule can be used to prevent synthesis of said molecule and therefore treat a disease mediated by said molecule, inhibitory antibodies were known in the art as per Parhami-Seren et al. and it would have been necessary to screen for such antibodies to identify them.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In

no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ron Schwadron, Ph.D./

Primary Examiner, Art Unit 1644